

REMARKS

Reconsideration is requested.

Claim 34 has been canceled, without prejudice. Claims 31-61 are pending.

The specification has been amended to include an Abstract, as published in the parent PCT application (PCT/FR99/01452 published as WO 99/65456). Withdrawal of the objection to the specification is requested.

A certified copy of the priority document FR 98/07802 is attached.

Acknowledgement of receipt of the same in the Examiner's next Action is requested.

The Section 112, second paragraph, rejection of claims 32, 33, 40, 50-53 and 59 is obviated by the above amendments. Withdrawal of the Section 112, second paragraph, rejection is requested.

The Section 103 rejection of claims 31-61 over Cameron (U.S. Patent No. 4,722,837) in view of Casmer (U.S. Patent No. 3,984,544), Kligman (U.S. Patent No. 5,998,395) and Cauwet (U.S. Patent No. 5,661,118) is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing comments.

Cameron describes a medicated shampoo composition for treating scalp disorders such as flaking, scaling, dandruff, psoriasis, eczema and seborrhea (col. 1 lines 57-59). It comprises pharmacologically acceptable ingredients including:

0.1-0.5 % by weight of hydrocortisone in combination with

2.5-5 % by weight of colloidal sulfur,

in a shampoo base (col. 1, lines 59-67).

The shampoo base preferably comprises a detergent (the term "detergent" being used in the singular and not in the plural) selected from lauryl sulfate salt, laureth sulfate salt, amphoteric surfactant and a betaine (col. 2, lines 2 1-26).

Cameron discloses the use of one detergent as above-mentioned. Only one anionic surfactant (sodium C₁₄₋₁₆ olefin sulfonate) is contained in Examples I and II, and no betaine nor any other amphoteric surfactant are exemplified. Consequently, this document does not teach the combination of an anionic surfactant and an amphoteric surfactant as mentioned by the Examiner. Clarification is requested in this regard in the event the rejection is maintained.

Moreover, Cameron does not describe retinoid or propenetrating agents.

Therefore, this document neither teaches nor suggests the combination of:

-at least one active principle chosen from the group consisting of corticoids and retinoids,

-at least one anionic surfactant,

-at least one amphoteric surfactant, and

-at least one propenetrating agent,

in order to obtain a foam which exhibits improved characteristics of volume and compactness.

Casmer describes novel retinoic acid esters of steroids of the pregnane series and their use in treating acne vulgaris which is a skin disorder.

Thus, Casmer discloses novel active principles for treating acne vulgaris (and not scalp disorders) and compositions which comprise a steroidal retinoate together with a

compounds
properties are not
distinct

non-toxic, pharmaceutically carrier (col. 10, lines 12-15). The steroidal retinoates are conveniently applied in a liquid solvent (col 10, lines 26-31).

Example 14 exemplifies topical pharmaceutical compositions. The different exemplified compositions are in the form of creams, ointments, solutions, lotions and gels. Isopropanol is in particular used in examples 14 C (3) and 14 D (1) as solvent and not as propenetrating agent. Casmer only teaches novel active principles for treating acne vulgaris, which are not irritating to the skin as compared with retinoic acid.

Consequently, Casmer et al never suggest a foaming composition for washing and treating scalp and/or hair comprising:

- at least one active principle chosen from the group consisting of corticoids and retinoids,
- at least one anionic surfactant,
- at least one amphoteric surfactant, and
- at least one propenetrating agent,

in order to obtain a foam which exhibits improved characteristics of volume and compactness.

(Kligman) describes methods of treating inflammatory dermatosis, and more particularly the synergistic effect of corticosteroids and retinoids in the treatment of skin diseases (col. 1, lines 15-16, col.3, lines 41-45). They are applied simultaneously in a single composition which uses a carrier pharmaceutically acceptable for both the retinoid and corticosteroid.

Among the disorders which can be effectively treated according to this document,

*not limited to
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the various forms of inflammatory acne (col. 4, lines 56-58) are exemplified.

not
limited to
exemplified

The two following compositions are exemplified:

(1) 0.1 % by weight of triamcinolone acetonide and
0.1 % by weight of tretinoin,

or

(2) 0.05 % by weight of clobetasol propionate and
0.1 % by weight of tretinoin,

in a cream base.

Consequently, Kligman et al never suggest a foaming composition for washing
and treating scalp and/or hair comprising:

-at least one active principle chosen from the group consisting of corticoids and
retinoids,

-at least one anionic surfactant,

-at least one amphoteric surfactant, and

-at least one propenetrating agent.

Accordingly, Cameron et al disclose a medicated shampoo composition for
treating scalp disorders comprising incorporating a corticoid in combination with
colloidal sulphur in a shampoo base which comprises a detergent. Casmer et al teach a
new retinoid non-irritating to the skin for treating vulgaris acne. Kligman et al. teach the
combination of a corticosteroid with a retinoid in the treatment of acne. There was then
absolutely no motivation for one of ordinary skill in the art to combine Cameron et al
relating to a medicated shampoo for treating scalp disorders with Casmer et al and

Kligman et al. relating to the treatment of skin diseases such as acne.

Cauwet describes compositions for washing and treating hair and/or skin, and more particularly conditioning shampoos. These compositions comprise:

- at least one anionic surfactant,
- at least one selected from zwitterionic and amphoteric surfactants,
- at least one polymer containing cationic groups, and
- at least one ceramide and/or glycosphingolipid

preferably in water (col. 14, lines 1-2 and examples).

This document neither teaches the combination of anionic and amphoteric surfactants with active principles and propenetrating agents as claimed.

The combination of the cationic polymer and ceramide and/or glycosphingolipid gives a synergy of the disentangling of hair.

Therefore one of ordinary skill in the art had absolutely no motivation to combine the reference relating to a disentangling shampoo with Kligman and Casmer relating to the treatment of skin diseases, such as acne with corticoids and steroids or with Cameron relating to a medicated shampoo containing hydrocortisone for treating scalp disorders.

One of ordinary skill in the art would not have been motivated to combine the teaching of Cauwet relating to a conditioning shampoo having good cosmetic properties with the teachings of Kligman and Casmer concerning the choice of suitable corticosteroids and retinoids for treating acne on skin, or with the teaching of Cameron relating to the choice of suitable active ingredients (hydrocortisone and colloidal

sulphur) for treating scalp disorders in order to obtain a foaming composition for washing and treating hair and/or scalp having at the same time improved characteristics of volume and compactness and good cosmetic performances, wherein the penetration of the active principle is improved, which is stable over time by preventing the precipitation of the active principles.

Thus, the invention, as claimed, would not have been *prima facie* obvious over the cited references to one of ordinary skill in the art at the time the invention was made.

Withdrawal of the Section 103 rejection of claims 31-61 is requested.

In view of the above, the claims are submitted to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

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MARKED UP CLAIMS

32. (Amended) A composition according to Claim 31, wherein the corticoid is selected from the group consisting of at least one of alclometasone dipropionate, amcinonide, beclometasone dipropionate, betamethasone benzoate, betamethasone dipropionate, betamethasone valerate, budesonide, clobetasol propionate, [preferably clobetasol 17-propionate,] clobetasol butyrate, desonide, desoximetasone, dexamethasone, diflorasone diacetate, difluocortolone valerate, flurandrenolone, fluprednidene acetate, fluocortolone, fluocortin butyl, fluocinonide, fluocinolone acetonide, flucorolone acetonide, flumetasone pivalate, feudiline hydrochloride, flumetholon, halcinonide, hydrocortisone, hydrocortisone acetate, hydrocortisone butyrate, hydrocortisone valerate, methylprednisolone acetate, mometasone furoate, methylprednisolone, prednisolone, triamcinolone acetonide, and pharmaceutically acceptable mixtures thereof.

33. (Amended) A composition according to Claim 31, wherein the retinoid is selected from the group consisting of all-trans-retinoic acid, adapalene, isotretinoin, retinol, [a retinol derivative] retinol acetate, retinol palmitate and retinol propionate, motretinide, etretinate, acitretin, zinc all-trans-retinoate, arotinoids and pharmaceutically acceptable mixtures thereof.

40. (Amended) A composition according to Claim 31, wherein the amphoteric surfactant is selected from the group consisting of a derivative of an aliphatic secondary or tertiary amine in which the aliphatic radical is a linear or branched chain comprising 8 to 22 carbon atoms and comprising at least one water-solubilizing anionic group, a

(C₈-C₂₀)alkyl betaine, a sulfobetaine, a (C₈-C₂₀)alkyl amido(C₁-C₆)alkyl betaine and a (C₈-C₂₀)alkyl amido(C₁-C₆)alkyl sulfobetaine.

42. (Amended) A composition according to Claim 41, wherein the amphoteric surfactant is selected from the group consisting of cocamidopropyl betaines, cocamidopropyl hydroxysultaine, and cocoyl betaines.

50. (Amended) A composition according to Claim 31, wherein the ratio of the proportion [as] of active material of the anionic surfactant to the proportion as active material of the amphoteric surfactant is between 1 and 20.

51. (Amended) A composition according to Claim 31, wherein the ratio of the proportion [as] of active material of the anionic surfactant to the proportion of the propenetrating agents is between 0.1 and 10.

52. (Amended) A composition according to Claim 31, wherein the composition additionally comprises at least one cationic polymer selected from the group consisting of a quaternized protein, a polyamine, a polyaminoamide, a poly(quaternary ammonium), a polyalkyleneimine, a condensate of a polyamine and of epichlorohydrin, and a quaternary polyureylene [and a chitin derivative].

53. (Amended) A composition according to Claim 31, wherein the cationic polymer is selected from the group consisting of a quaternary cellulose ether [derivative], a cyclopolymer and a cationic polysaccharide.

59. (Amended) A composition according to Claim 31, in the form of liquids [or optionally thickened liquids].

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ABSTRACT OF THE DISCLOSURE

C' The invention concerns a foaming composition for washing and treating hair and/or scalp essentially characterised in that it contains in an aqueous medium: at least an active principle selected among corticoids and retinoids; at least an anionic surfactant; at least an amphoteric surfactant; and a pro-penetrating agent.
